Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

Evaluation of the efficacy and safety of stillen in comparison with pentoprazole in controlling the symptoms of gastro-myopic reflux in patients referred to the gastroenterology clinic of Baqiyatallah Hospital

Protocol summary

Study aim

Aim of this was evaluation of acetylene in comparison with oral pantoprazole in controlling gastro-esophageal reflux symptoms in patients referred to gastroenterology clinic of Baqiyatallah Hospital.

Design

This assessment was a phase 3 clinical trial and was conducted on patients with gastroesophageal reflux disease. At first, symptoms were recorded according to RSI questionnaire. If they scored more than 13, reflux disease was diagnosed. Patients divided into two groups of 30, and each group received pentaprazole 40 mg daily before breakfast, first group received acetylene before bedtime, and second group continued to take same treatment as Pentoprazole, duration of protocol was 6 weeks. Patients in 3 and 6 weeks were evaluated for clinical manifestations.

Settings and conduct

This study was carried out as a clinical trial at gastroenterology clinic of Erfan Hospital in Tehran, also study will also be single blinded and patients will be blinded in study.

Participants/Inclusion and exclusion criteria

Patients completing an consent more than 18 years of age, non-smokers and approved for diagnosis of reflux disease with clinical and paraclinical findings are considered as a study group. Also patient's should not be in life-threatening, not participate in another clinical trial at same time and should not be treated with interfering drugs before intervention, they are considered as a research group. Also, pregnant patients, psychiatric and veterans, due to pulmonary symptoms, with any severe complications in use of medications, exacerbation of signs during study and treatment discontinuation, will be excluded from study.

Intervention groups

Intervention group: In this group, pantoprazole is used 40 mg before breakfast and acetylene 60 mg before bedtime. Control group: In this group, pantoprazole is used 40 mg before breakfast.

Main outcome variables

Gastro-esophageal reflux

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180422039378N1**
Registration date: **2018-06-11, 1397/03/21**
Registration timing: **retrospective**

Last update: **2018-06-11, 1397/03/21**
Update count: **0**

Registration date

2018-06-11, 1397/03/21

Registrant information

Name

nasrollah shafighi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 8126 0043

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-04-19, 1396/01/30

Expected recruitment end date

2018-02-18, 1396/11/29

Actual recruitment start date
2017-04-20, 1396/01/31
Actual recruitment end date
2018-02-19, 1396/11/30
Trial completion date
empty

Scientific title
Evaluation of the efficacy and safety of stillen in comparison with pentoprazole in controlling the symptoms of gastro-myopic reflux in patients referred to the gastroenterology clinic of Baqiyatallah Hospital

Public title
Evaluation of the effect of acetylene drug in comparison with oral administration of pantoprazole in controlling symptoms of gastro-esophageal reflux.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Completion of informed consent form Diagnosis of reflux disease is confirmed by clinical and paraclinical findings. The patient's condition is not life-threatening. Do not participate in another clinical trial at the same time. Do not interact with medication before intervention. Like beta blocker inhibitors and herbal medicines or drugs that are harmful for treatment of reflux, such as theophylline, and others. Age over 18 years No smoking in the past Not pregnancy Failure to enter the plan for patients with psychiatric and veterinary injuries due to pulmonary symptoms
Exclusion criteria:
The occurrence of severe drug-related symptoms and severe hypersensitivity to drugs that can not be controlled. Signs and symptoms of the patient have worsened during the study. Those patients who have not consumed their medication for more than a week. History of chemical gas and severe pulmonary disease. Pregnant or intending to have a pregnancy Presence and observation of drug interactions
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **60**
Actual sample size reached: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to randomization we will use the block method, based on this two lists of patients are provided and each list is placed in one of the groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
This means that patients in groups do not know the used drugs.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Baqiyatallah University of Medical Sciences
Street address
Vanak Square, Mulla Sadra St.
City
Tehran
Province
Tehran
Postal code
88191248
Approval date
2017-04-09, 1396/01/20
Ethics committee reference number
IR.BMSC.REC.1396.445

Health conditions studied

1

Description of health condition studied
Gastro-esophageal reflux
ICD-10 code
K21
ICD-10 code description
Gastro-esophageal reflux disease

Primary outcomes

1

Description
Symptoms of Gastro-esophageal reflux Disease
Timepoint
Before starting treatment, as well as at 3 and 6 weeks after starting treatment
Method of measurement
Interview with patients using reflux symptom index questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group, pantoprazole 40 mg before breakfast and acetylene 60 mg before bedtime, is used.
Category
Treatment - Drugs

2

Description
Control group: In this group, pantoprazole 40 mg before breakfast, is used.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Erfan Hospital
Full name of responsible person
Dr. Hossein Khedmat
Street address
Sheikh Bahay Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bagheiat-allah University of Medical Sciences
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Gholam Hossein Alishiri
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bagheiat-allah University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Dr. Hossein Khammat
Position
professor of Gastroenterologist
Latest degree
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Person responsible for updating data

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Full name of responsible person

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Position

Gastroenterologist

Latest degree

Subspecialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available